

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 07/23/2012
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001129		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 04/04/2012	
NAME OF PROVIDER OR SUPPLIER CARMEL AMBULATORY SURGERY CENTER LLC, THE				STREET ADDRESS, CITY, STATE, ZIP CODE 13421 OLD MERIDIAN ST CARMEL, IN 46032			
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S0000	<p>The visit was for a licensure survey.</p> <p>Facility Number: 003497</p> <p>Survey Date: 4-02-12 to 4-04-12</p> <p>Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor</p> <p>Karilyn Tretter, RN Public Health Nurse Surveyor</p> <p>QA: cloughlin 04/13/12</p> <p>6/22/12 Revised due to IDR</p>		S0000				

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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S0156	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (E)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(E) Maintenance of current job descriptions with reporting responsibilities for all personnel and annual performance evaluations, based on a job description, for each employee providing direct patient care or support services, including contract and agency personnel, who are not subject to a clinical privileging process.</p> <p>Based on document review and interview, the chief executive officer failed to maintain the job descriptions for all employees at the center.</p> <p>Findings:</p> <p>1. The policy/procedure Position Description: Executive Director (approved 3-12) indicated the following: " Assure that job descriptions are developed and maintained for all positions in the center ...hire, train, and manage the Director of Clinical Operations ...[and] ...designate physician or Director of Clinical Operations to be responsible for Center Operations for any period of absence from the center. "</p>		S0156	<p>The Executive Director did not say the position was vacated in 2004. The last person in that position died in January, 2012. The Executive Director repeatedly explained that the OR Charge Nurse fills that role. The Executive Director's job description has been changed to reflect the change from Clinical Director to OR Charge Nurse. The Executive Director has made the change and is responsible for compliance.</p>		04/23/2012	

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	2. During an interview on 4-04-12 at 1000 hours, staff A1 confirmed that the position of Clinical Director had been vacant since the center opened in 2004, that the position description failed to indicate the current chain of command when the executive is absent, and that the job description was not up-to-date.						

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S0166	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (I)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(I) Requiring all services to have policies and procedures that are updated as needed and reviewed at least triennially.</p> <p>Based upon document review and interview, the center failed to maintain and update its policies/procedures as needed and reviewed at least every three years.</p> <p>Findings:</p> <p>1. The policy/procedure Operation of Zoll Pacemaker/Defibrillator/Monitor (approved 3-12) indicated the following: " The nursing staff of the center shall be trained in the operation and care of the Life Pak 9. "</p> <p>2. During an interview on 4-04-12 at 1100 hours, staff A1 and A3 confirmed that the center had not used a Life Pak 9 for several years and that policy/procedure failed to indicate the current equipment in use at the center.</p>		S0166	<p>The Executive Director has changed the one place in the defibrillator policy where LifePak 9 was mentioned. The Executive Director is responsible for compliance.</p>		04/23/2012	

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S0172	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (L)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(L) Maintaining personnel records for each employee of the center which include personal data, education and experience, evidence of participation in job related educational activities, and records of employees which relate to post offer and subsequent physical examinations, immunizations, and tuberculin tests or chest x-rays, as applicable.</p> <p>Based on document review and interview, the center failed to maintain its personnel health records regarding tuberculin (Tb) tests for 13 of 26 health files reviewed. (staff MD3, MD5, MD11, MD12, MD14, AH21, AH22, AH24, AH26, HK2, HK3, HK4, and HK5).</p> <p>Findings included:</p> <p>1. The Centers for Disease Control and Prevention (CDC) <u>Fact Sheets:</u> <u>Tuberculosis: General Information.</u> July 2007 indicated the following: "The [PPD] skin test reaction should be read between 48 and 72 hours after administration. A patient who does not return within 72 hours will need to be</p>	S0172	The Executive Director has changed the TB form to include date and time. The Executive Director will send a letter to other hospitals providing TB tests for physicians that time is now a requirement. All cited were medical staff or allied health providers medical staff whose TB tests were performed in other institutions. Surveyor did not ask for Housekeeping TB tests. The Housekeeping TB tests are current. The Executive Director will oversee compliance.	04/23/2012			

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	<p>rescheduled for another skin test."</p> <p>2. The policy/procedure Tuberculosis Infection Control Program (approved 3-12) lacked a provision ensuring that acceptable Tb skin test documentation must include a date and time for administration and post-administration reading.</p> <p>3. Review of 9 personnel health files (staff MD3, MD5, MD11, MD12, MD14, AH21, AH22, AH24, and AH26) indicated each had a PPD test placed in 2011 and documentation failed to indicate the time of day that the skin test was examined for a possible reaction.</p> <p>4. Review of 4 housekeeping staff records failed to indicate a date or time test was administered and read and failed to indicate that a test was administered.</p> <p>5. During an interview on 4-03-12 at 1300 hours, staff A3 confirmed that the policy/procedure failed to ensure the test was read properly and confirmed that the 13 personnel health files lacked documentation indicating the time when the test was read in accordance with CDC requirements.</p>						

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S0176	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (M)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(M) Demonstrating and documenting personnel competency in fulfilling assigned responsibilities and verifying in-service in special procedures.</p> <p>Based on document review and interview, the facility failed to document contracted housekeeping personnel competency for cleaning and disinfecting surgical and patient care areas at the center for three contracted employees.</p> <p>Findings:</p> <p>1. The policy/procedure Housekeeping Policy (approved 3-12) failed to ensure that housekeeping personnel files contain documentation of competency by center staff observation for cleaning the surgical and patient care areas and failed to ensure that the contracted housekeeping performance is consistent with infection prevention objectives (cleaning and disinfecting high touch surfaces, cleaning from high to low and least contaminated to most contaminated, use gloves when performing cleaning tasks or handling</p>	S0176	Housekeeping is a contracted service. The Executive Director does make sure basic in services are given to those individuals employed by the service. The Executive Director observes their work randomly and unannounced and their service is evaluated. The Executive Director discusses with contracted company if any questions are raised regarding one of their employees. The service has an excellent crew currently. The Executive Director has updated the Housekeeping policy and will continue to oversee compliance.	04/23/2012			

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	<p>hazardous materials, proper operating room attire) and performed according to identified criteria to validate performance by each staff as recommended by the Association of PeriOperative Registered Nurses (AORN) 2007 Recommended Practices for Environmental Cleaning in the Perioperative Setting.</p> <p>2. The Administrative document Housekeeping Observation 2011 failed to indicate the specific standards, practices and objectives being observed and evaluated and failed to indicate what individual was observed for each occasion.</p> <p>3. During an interview on 4-03-12 at 1315 hours, staff A9 confirmed that the 3 housekeeping personnel files lacked competency validation by center staff for cleaning surgical and patient care areas and confirmed that the housekeeping policy lacked a checklist to validate housekeeping competency in cleaning and disinfecting at the center as recommended by AORN.</p>						

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S0226	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(e)(3)</p> <p>The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following:</p> <p>(3) Ensure that the center maintains a list of all contracted services, including the scope and nature of the services provided.</p> <p>Based on document review, the facility failed to maintain a list of all contracted services, including the scope and nature of services provided, for 3 of 20 services.</p> <p>Findings:</p> <p>1. Review of a list of contracted services provided by staff A1 failed to indicate a service provider for the medical gas system testing and certification, radiologic equipment calibration and certification, and the heating and air conditioning service.</p> <p>2. Review of facility documentation indicated that the medical gas system testing and certification was provided on 7-14-11 by V1, radiologic equipment calibration and certification was performed on 1-18-12 by medical physicist V2, and air filter maintenance</p>	S0226	The Executive Director has added medical gas and radiology equipment calibration to contracted services list. HVAC is not contracted through facility but through Barrett & Stokely who provides building maintenance. Barrett and Stokely has been provided on our List of Service Agreements. The Executive Director is responsible for compliance.	04/23/2012			

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	on 3-18-12 by V3. 3. On 4-04-12 at 1215 hours, staff A1 confirmed that the center failed to maintain a list of contracted services.						

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S0310	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)(1)</p> <p>The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:</p> <p>(1) All services, including services furnished by a contractor.</p> <p>Based on document review and interview, the center failed to ensure that contracted services were evaluated using specific and objective standards through its quality assurance (QA) program for 18 contracted services.</p> <p>Findings:</p> <p>1. The Evaluation of Contract Services QA 4th quarter 2011 Report failed to indicate specific and objective standards for evaluating each service and failed to identify the vendor name under the contract services heading to ensure accountability for each contracted service recommended for contract renewal. The report failed to indicate that each service met each standard (or not) based on the information provided for review.</p> <p>2. During an interview on 4-04-12 at 1215 hours, staff A1 confirmed that the Evaluation of Contract Services Report</p>		S0310	<p>The Executive Director evaluates services quarterly and presents to QA meetings. On January 24, 2012, the form changed. There is only one company performing each service and it is specifically listed on Contract Service List. The Executive Director is responsible for compliance.</p>		04/23/2012	

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	lacked measureable and objective standards, failed to identify the provider being evaluated and failed to document the effectiveness of each contracted service.						

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S0328	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(b)</p> <p>(b) The center shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows:</p> <p>(1) The action must be documented. (2) The outcome of the action must be documented as to its effectiveness, continued follow-up, and impact on patient care.</p> <p>Based on document review and interview, the center failed to document an appropriate action in response to opportunities for improvement identified through the Quality Assurance (QA) program and failed to document the effectiveness of corrective action indicated by the QA Committee in response to an opportunity for improvement.</p> <p>Findings:</p> <p>1. QA minutes dated 1-18-11 failed to indicate a committee recommendation or corrective action regarding a study conducted on sharps injuries and the individual identified through the study. The minutes indicated the committee action to research available literature and establish guidelines for post-operative</p>		S0328	<p>The Executive Director will oversee that follow up on QA studies be conducted by the following year and improve the QA minutes documentation. The QA responses are on the actual QA stuides. The Executive Director will make a better effort to reflect the responses in the minutes. The Executive Director will make sure that Infection Control Preventionist's report is identified as such to reflect the supporting documents.</p>		04/23/2012	

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	<p>infection reporting by medical staff and QA minutes for subsequent meetings failed to indicate that either issue was reviewed and resolved or required further committee action.</p> <p>2. QA minutes dated 4-19-11 indicated that a recovery room study involving documentation of a pain [medication effectiveness] response did not achieve the intended goal of 100% compliance and that the study would be repeated later in the year. QA minutes dated 7-19-11, 10-11-11, and 1-24-12 failed to indicate the study was repeated and reviewed by the committee. The minutes indicated that staff A1 was to conduct a feasibility and financial impact study involving an increase in the surgical patient weight limit from 350 lbs to 420 lbs and subsequent QA meeting minutes failed to indicate a study was conducted and reported to the committee.</p> <p>3. QA minutes dated 7-19-11 indicated that a medication study determined that 13% of ordered and administered medications were not billed and staff were educated regarding the medication issue. The minutes indicated that a study would be conducted in the future and subsequent meeting minutes failed to indicate a study was conducted and reported to the committee.</p>						

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	<p>4. QA minutes dated 10-11-11 failed to indicate a committee response or recommendation regarding a study involving delays in surgery start times.</p> <p>5. QA minutes dated 1-28-12 failed to indicate a recommendation to identify the vendor name under the contract services heading to ensure accountability for each contracted service recommended for contract renewal on the Contract Services Spreadsheet. The minutes failed to indicate a recommendation to identify the role of the Infection Prevention Nurse in the Infection Control Plan as approved.</p> <p>6. During an interview on 4-04-12 at 1350 hours, staff A1 indicated that ongoing QA review was performed by A1 looking back at prior QA minutes to identify any issues that may require further action by the committee. Staff A1 confirmed the QA program failed to document an action for the indicated concerns and failed to ensure program accountability by not documenting the action outcome or follow-up and its effectiveness for the QA studies described in the minutes.</p>						

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S0332	<p>410 IAC 15-2.4-2.2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2.2(a)(1)</p> <p>Sec. 2.2. (a) The center's quality assessment and improvement program under section 2 of this rule shall include the following: (1) A process for determining the occurrence of the following reportable events within the center: (A) The following surgical events: (i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations: (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent; or both (ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. (iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations: (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent; or both (iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded: (AA) Objects intentionally implanted as part of a planned intervention. (BB) Objects present before surgery that were intentionally retained.</p>						

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	<p>(CC) Objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention, such as microneedles or broken screws.</p> <p>(v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.</p> <p>(B) The following product or device events:</p> <p>(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the center. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.</p> <p>(ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:</p> <p>(AA) Catheters.</p> <p>(BB) Drains and other specialized tubes.</p> <p>(CC) Infusion pumps.</p> <p>(DD) Ventilators.</p> <p>(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the center. Excluded are deaths or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.</p> <p>(C) The following patient protection events:</p> <p>(i) Infant discharged to the wrong person.</p> <p>(ii) Patient death or serious disability associated with patient elopement.</p> <p>(iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the center, defined as events that result from patient actions after admission to</p>						

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	<p>the center. Excluded are deaths resulting from self inflicted injuries that were the reason for admission to the center.</p> <p>(D) The following care management events:</p> <p>(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:</p> <p>(AA) drug; (BB) dose; (CC) patient; (DD) time; (EE) rate; (FF) preparation; or (GG) route of administration.</p> <p>Excluded are reasonable differences in clinical judgment on drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug=drug interactions for which there is known potential for death or serious disability.</p> <p>(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products.</p> <p>(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the center. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:</p> <p>(AA) Pulmonary or amniotic fluid embolism. (BB) Acute fatty liver of pregnancy. (CC) Cardiomyopathy.</p> <p>(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the center.</p> <p>(v) Death or serious disability (kernicterus) associated with the failure to identify and treat hyperbilirubinemia in neonates.</p> <p>(vi) Stage 3 or 4 pressure ulcers acquired after admission to the center. Excluded is</p>						

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	<p>progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable because of the presence of eschar.</p> <p>(vii) Patient death or serious disability resulting from joint movement therapy performed in the center.</p> <p>(viii) Artificial insemination with the wrong donor sperm or wrong egg.</p> <p>(E) The following environmental events:</p> <p>(i) Patient death or serious disability associated with an electric shock while being cared for in the center.</p> <p>Excluded are events involving planned treatment, such as electrical countershock or elective cardioversion.</p> <p>(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:</p> <p>(AA) contains the wrong gas; or</p> <p>(BB) is contaminated by toxic substances.</p> <p>(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the center.</p> <p>(iv) Patient death or serious disability associated with a fall while being cared for in the center.</p> <p>(v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the center.</p> <p>(F) The following criminal events:</p> <p>(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.</p> <p>(ii) Abduction of a patient of any age.</p> <p>(iii) Sexual assault on a patient within or on the grounds of the center.</p> <p>(iv) Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the center.</p>						

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	<p>Based on document review and interview, the quality assurance (QA) program lacked a policy/procedure indicating the reportable events identified by State law 410 IAC 15-2.4-2.2 Reportable Events and failed to identify a reportable event occurrence at the center.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. On 4-02-12 at 0930 hours, staff A1 was requested to provide documentation indicating the events to be reported to the Indiana State Department of Health and none was provided prior to exit. 2. Documentation dated 10-10-11 indicated that a surgical procedure performed on patient P34 was not consistent with the documented informed consent and that an additional procedure was performed as a consequence of the surgical procedure performed on the patient. 3. During an interview on 4-04-12 at 1300 hours, staff A1 confirmed that the center lacked a policy/procedure for determining the occurrence of reportable events at the center and confirmed that the QA program failed to identify a reportable event occurrence. 		S0332	<p>The Executive Director developed a Policy and Procedure for Reportable Events to the Indiana State Department of Health. Policy and Procedure #13.14a. Research on specific patient found that surgeon's scheduler did not schedule correct procedure. Patient did receive the procedure she expected. Surveyor took the information and informed Executive Director that it was now reported. The Executive Director is responsible for compliance.</p>		04/23/2012	

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S0334	<p>410 IAC 15-2.4-2.2(a)(2) QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2.2(a)(2)</p> <p>(2) A process for reporting to the department each reportable event listed in subdivision (1) that is determined by the center's quality assessment and improvement program to have occurred within the center.</p> <p>(b) Subject to subsection (e), the process for determining the occurrence of the reportable events listed in subsection (a)(1) by the center's quality assessment and improvement program shall be designed by the center to accurately determine the occurrence of any of the reportable events listed in subsection (a)(1) within the center in a timely manner.</p> <p>(c) Subject to subsection (e), the process for reporting the occurrence of a reportable event listed in subsection (a)(1) shall comply with the following:</p> <p>(1) The report shall:</p> <p>(A) be made to the department;</p> <p>(B) be submitted not later than fifteen (15) working days after the reportable event is determined to have occurred by the center's quality assessment and improvement program;</p> <p>(C) be submitted not later than four (4) months after the potential reportable event is brought to the program's attention; and (D) identify the reportable event, the quarter of occurrence, and the center, but shall not include any identifying information for any:</p> <p>(i) patient;</p> <p>(ii) individual licensed under IC 25; or</p> <p>(iii) center employee involved;</p> <p>or any other information.</p> <p>(2) A potential reportable event may be identified by a center that:</p>						

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	<p>(A) receives a patient as a transfer; or (b) admits a patient subsequent to discharge; from another health care facility subject to a reportable event requirement. In the event that a center identifies a potential reportable event originating from another health care facility subject to a reportable event requirement, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.</p> <p>(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.</p> <p>(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.</p> <p>(d) The center's report of a reportable event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of reportable events occurring within each center. The department's public report will be issued annually.</p> <p>(e) Any serious reportable listed in subsection (a)(1) that: (1) is determined to have occurred within the center between: (A) January 1, 2009; and (B) the effective date of this rule; and (2) has not been previously reported; must be reported within five (5) days of the effective date of this rule. (Indiana State Department of Health; 410 IAC 15-2.4-2.2)</p> <p>Based on document review and interview,</p>	S0334	The Executive Director developed	04/23/2012			

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	<p>the center lacked a process for reporting events identified by state law 410 IAC 15-2.4-2.2 (a)(1) Reportable Events that were identified by the quality assurance (QA) program to have occurred at the center.</p> <p>Findings:</p> <p>1. On 4-02-12 at 0930 hours, staff A1 was requested to provide documentation of the process for reporting events to the Indiana State Department of Health (ISDH) and none was provided prior to exit.</p> <p>2. The policy/procedure Quality Assurance Plan (approved 3-12) lacked a provision indicating the process identified by state law 410 IAC 15-2.4-2.2(a)(2) for reporting events to the ISDH.</p> <p>3. During an interview on 4-04-12 at 1300 hours, staff A1 confirmed that the center lacked a policy/procedure for reporting events to the ISDH.</p>			<p>Policy and Procedure of Reportable Events (Policy 13.14a). The Executive Director is responsible for compliance.</p>			

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S0400	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(a)</p> <p>(a) The center shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and visitors.</p> <p>Based on document review and interview, the center failed to ensure a safe and healthful environment that minimized risk and infection exposure to patients, staff, and visitors.</p> <p>Findings:</p> <p>1. The policy/procedure Housekeeping Policy (approved 3-12) failed to indicate infection prevention objectives (clean and disinfect all high touch surfaces, clean from high to low and least contaminated to most contaminated, use gloves when performing cleaning tasks or handling hazardous materials, required operating room attire) and failed to ensure that only infection control committee-approved cleaning products will be used by contracted housekeeping staff for cleaning and disinfecting at the center.</p> <p>2. On 4-03-12 at 1215 hours, staff A1 was requested to provide a list of housekeeping products used by the contracted service and approved by the infection control committee and none was</p>		S0400	<p>The Executive Director presented to Infection Control/Quality Assurance committee the list of cleaning products used in the facility at the April meeting as was told to the Surveyor. The Housekeeping Policy was updated by Infection Control Preventionist on 4/23/12. The Executive Director is responsible for compliance.</p>		04/17/2012	

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	<p>provided prior to exit.</p> <p>3. During an interview on 4-04-12 at 1130 hours, staff A1 confirmed that the policy/procedure failed to indicate the infection prevention objectives to minimize disease transmission at the center and failed to ensure that only approved products were used by the contracted housekeeping staff.</p>						

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S0414	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(1)</p> <p>(f) The center shall establish a committee to monitor and guide the infection control program in the center as follows:</p> <p>(1) The infection control committee shall be a center or medical staff committee, that meets at least quarterly, with membership that includes, but is not limited to, the following:</p> <p>(A) The person directly responsible for management of the infection surveillance, prevention, and control program as established in subsection (d).</p> <p>(B) A representative from the medical staff.</p> <p>(C) A representative from the nursing staff.</p> <p>(D) Consultants from other appropriate services within the center as needed.</p> <p>Based on document review and interview, the infection control committee lacked a person qualified by training in infection control as responsible for the ongoing infection control activities.</p> <p>Findings included:</p> <p>1. Review of the Infection Control Plan (approved 3-12) and Quality Assurance Plan (approved 3-12) failed to indicate a</p>	S0414	The job description of the Infection Control Preventionist describes that this position is responsible for ongoing management of infection prevention and surveillance. The job description of the Infection Control Preventionist was in the policies and procedures book but was not indicated on the Table of Contents. The Executive Director had Table of Contents for the Policy and Procedures Manual updated to include the Infection	04/23/2012			

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	<p>person directly responsible for the ongoing management of infection prevention and surveillance.</p> <p>2. The Policies and Procedure Manual (approved 3-12) table of contents failed to indicate a job description titled Infection Control Preventionist and documentation provided by A1 lacked a policy number to authenticate the position description.</p> <p>3. The Quality Assurance meeting minutes for 2011 and 1-24-2012 failed to indicate that the Infection Control Preventionist had attended the committee meetings.</p> <p>4. On 4-04-12 at 1350 hours, staff A1 confirmed that the Infection Control Plan lacked a provision for the infection control officer and confirmed that the infection preventionist had not been attending the committee meetings.</p>		Control Preventionist job description. In 2011, the Infection Control Preventionist submitted a report at each QA Meeting. In January 2012, the Infection Control Preventionist was invited but was on medical leave as indicated specifically in the minutes. However, she did submit a report. The Infection Control Preventionist did attend the 4/17/2012 meeting. The Executive Director will make sure Infection Control Preventionist attends QA meetings.				

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S0422	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(C)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(C) Reviewing employee exposure incidents and making appropriate recommendations to minimize risk.</p> <p>Based on document review and interview, the center failed to identify at-risk health care workers and ensure that risk of potential exposure was minimized for all employees at the center.</p> <p>Findings:</p> <p>1. The policy/procedure Blood Borne Disease Exposure Control Plan and Universal Precautions (approved 3-12) failed to identify housekeeping staff as at-risk employees in the Risk Assessment categories and failed to ensure that housekeeping staff were informed of the availability of center policy/procedures to minimize exposure risk as recommended by the Association of PeriOperative Registered Nurses (AORN) 2007 Recommended Practices for Environmental Cleaning in the Perioperative Setting.</p> <p>2. During an interview on 4-03-12 at 1230 hours, staff A9 confirmed that the</p>	S0422	The policy is written for CASC employees. Housekeeping is a contracted service. The Executive Director will make sure that the Housekeeping service has yearly in service on Hazard Communications.	04/23/2012			

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S0640	<p>policy/procedure failed to indicate the housekeeping personnel in the risk assessment and failed to ensure that the housekeeping staff received information from the center to minimize exposure risk as recommended by AORN.</p> <p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(e)(1)</p> <p>(e) All entries in the medical record must be as follows:</p> <p>(1) Legible and complete.</p> <p>Based upon document review and interview, the center lacked a policy/procedure ensuring that all entries in the medical record (MR) were legible.</p> <p>Findings:</p> <p>1. The policy/procedure Charting Standards (approved 3-12) and Completeness of Medical Records (approved 3-12) lacked a provision for verifying illegible entries in the MR.</p> <p>2. On 4-04-12 at 1330 hours, staff A1 confirmed the center lacked a policy/procedure for verifying illegible information in the patient record.</p>		S0640	<p>The Executive Director updated a policy and procedure to define legibility. The Executive Director is responsible for compliance.</p>		04/23/2012	

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S0646	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(e)(3)</p> <p>All entries in the medical record must be as follows:</p> <p>(3) Authenticated and dated in accordance with section 4(b)(3)(N) of this rule.</p> <p>Based upon document review and interview, the center lacked a policy/procedure to ensure all entries in the medical record (MR) were dated and timed when signed by the person making the entry.</p> <p>Findings:</p> <p>1. On 4-02-12 at 0930 hours, staff A1 was requested to provide a policy/procedure regarding verbal orders and none was provided prior to exit.</p> <p>2. The Rules and Regulations of the Medical Staff (approved 3-12) indicated the following: " Orders dictated over the telephone shall be signed by the Registered Nurse to whom dictated, with the name of the physician, who shall sign the order within 7 days of implementation. " The medical staff rule lacked the requirement for dating and timing the order when authenticated by the physician to validate compliance with</p>		S0646	<p>The Executive Director updated a policy to include date and time of physician's signature. The Executive Director is responsible for compliance.</p>		04/23/2012	

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	<p>the requirement.</p> <p>3. On 4-04-12 at 1330 hours, staff A1 confirmed the medical staff rule failed to ensure all MR entries would be dated and timed when authenticated.</p>						

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S0780	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(N)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(N) A requirement that all practitioner orders are in writing or acceptable computerized form and must be authenticated by a responsible practitioner as allowed by medical staff policies and within the time frames specified by the medical staff and center policy not to exceed thirty (30) days.</p> <p>Based upon document review and interview, the center lacked a uniform policy/procedure for authenticating verbal orders in the medical record (MR).</p> <p>Findings:</p> <p>1. The Rules and Regulations of the Medical Staff (approved 3-12) indicated the following: " Orders dictated over the telephone shall be signed by the Registered Nurse to whom dictated, with the name of the physician, who shall sign the order within 7 days of implementation. " The medical staff rule lacked a requirement for dating and timing the order when authenticated by the physician to validate compliance with</p>		S0780	<p>The Executive Director updated both policies for consistency and reflected date and time. Also, the Executive Director will oversee compliance.</p>		04/23/2012	

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	<p>the requirement.</p> <p>2. The policy/procedure Pharmacy Services (approved 3-12) indicated the following: " the staff physician ...may verbally prescribe ...such prescription shall be entered on the Physician ' s Orders in the Patient ' s Chart, initialed by the nurse and signed by the physician within 24 hours. " The policy/procedure lacked a requirement for dating and timing the order when authenticated by the physician to validate compliance with the policy/procedure.</p> <p>3. During an interview on 4-04-12 at 1330 hours, staff A1 confirmed that the center lacked a uniform standard for authenticating verbal orders in the MR.</p>						

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S0862	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(d)(2)(C)</p> <p>Requirement for surgical services include:</p> <p>(2) Surgical services shall develop, implement, and maintain written policies governing surgical care designed to assure the achievement and maintenance of standards of medical and patient care as follows:</p> <p>(C) A provision for the following equipment and supplies to be available to the surgical and recovery areas:</p> <p>(i) Emergency call system. (ii) Oxygen. (iii) Resuscitation equipment. (iv) Defibrillator. (v) Cardiac monitors. (vi) Tracheostomy set. (vii) Oximeter. (viii) Suction equipment. (ix) Other supplies and equipment specified by the medical staff.</p> <p>Based on document review and interview, the center failed to ensure that required emergency equipment was available for use for 1 of 9 required emergency equipment.</p> <p>Findings:</p> <p>1. The policy/procedure Crash Cart Content (approved 3-12), Code Blue</p>		S0862	<p>The Regulation states that the oximeter is "Available to surgery and recovery areas." There is an oximeter in each patient room, every PACU bed, and in each OR. There are also extra oximeters not assigned to specific areas for use anywhere one is needed. The OR Charge Nurse and the Recovery Room Charge Nurse ensure the oximeters are in working condition.</p>		04/23/2012	

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	<p>Condition and Response (approved 3-12) and Daily Checklist - Crash Cart & Critical Equipment (approved 3-12) failed to indicate that an oximeter was available for use in the event of an emergency.</p> <p>2. During an interview on 4-04-12 at 1330 hours, staff A1 confirmed that the policy/procedures lacked the required equipment.</p>						

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S1180	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(1)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(1) A review of safety functions by a committee appointed by the chief executive officer that includes representatives from administration and patient care services.</p> <p>Based on document review and interview, the center failed to establish a safety management program that included a review of safety functions by a committee appointed by the chief executive officer and included representatives from administration and patient care services.</p> <p>Findings:</p> <p>1. On 4-02-12 at 0930 hours, staff A1 was requested to provide documentation of a safety management program including committee minutes and a designated safety officer and none was provided prior to exit.</p> <p>2. The policy/procedure Table of Contents failed to indicate a policy/procedure regarding Safety Plan/Program.</p> <p>3. The policy/procedure Quality Assurance Plan (approved 3-12) failed to indicate a Safety Committee structure and membership appointed by the chief executive including representatives from administration and patient care services, failed to indicate a frequency for safety committee meetings, and failed to establish participation of the required committee members in the safety program.</p> <p>4. During an interview on 4-04-12 at 1100 hours, staff A3 confirmed that the center lacked a safety management program including a safety officer and</p>		S1180	<p>The Executive Director did not say there was no safety program. The program is in the Table of Contents as Risk Management. The Risk Management committee is the QA Committee as stated in the policy. The Executive Director will continue to include in Quality Assurance Minutes all Safety (Risk Management) issues. QA meets quarterly.</p>		04/23/2012	

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	representatives from administration and patient care services and lacked documentation of safety committee meetings that validated participation by committee members in the safety program.						

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S1184	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 2.5-7(c)(3)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(3) The safety program includes, but is not limited to, the following:</p> <p>(A) Patient safety. (B) Health care worker safety. (C) Public and visitor safety.</p> <p>Based on document review and interview, the center failed to establish a safety management program that included provisions for patient, public, visitor, and health care worker safety.</p> <p>Findings:</p> <p>1. On 4-02-12 at 0930 hours, staff A1 was requested to provide documentation of a safety management program that included provisions for patient, public, visitor and health care worker safety and none was provided prior to exit.</p> <p>2. The policy/procedure Quality Assurance Plan (approved 3-12) failed to indicate a Safety Program that integrated the elements of patient safety, health care worker safety, and public and visitor safety in a comprehensive plan to ensure a safe environment of care.</p>	S1184	<p>The surveyor did not understand that our QA Committee includes Safety issues known as Risk Management. The Executive Director will continue to assure the Risk Management is included in QA minutes. Risk Management does include patient safety, health care worker safety, and public and visitor safety.</p>		04/23/2012		

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	3. During an interview on 4-04-12 at 1100 hours, staff A3 confirmed that the center failed to develop a written safety management plan with specific provisions for patient safety, public and visitor safety, and health care worker safety to comply with state requirements.						

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S1198	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(6)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(6) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.</p> <p>Based upon document review and interview, the center lacked documentation of a disaster preparedness and participation with community, state and federal emergency and disaster preparedness agencies.</p> <p>Findings:</p> <p>1. The policy/procedure Emergency Operations (approved 3-12) indicated the following: "It is therefore the policy of the center to not participate in the event of an external disaster and to so notify and inform appropriate community/governmental parties. " The policy/procedure failed to indicate the state requirement for coordinating a response with appropriate agencies in the event of a community disaster, lacked a provision for sheltering in place, failed to indicate the center response for specific emergency types (Bomb, Chemical Spill,</p>		S1198	<p>The Executive Director updated policy as we are participating in external disasters. The Executive Director will continue to upgrade policy and procedures working with St. Vincent's Carmel. The Disaster Report was not a drill this year; it was an actual event. On Friday, March 2, 2012, Hamilton County was issued a Tornado Warning. The Center took the appropriate action. This actual event took the place of our annual drill. Fire Drills are performed quarterly and the Executive Director will oversee compliance.</p>		04/23/2012	

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	<p>Tornado) listed on the Emergency Drill Checklist, and lacked a provision for conducting an annual disaster drill at the center.</p> <p>2. During an interview on 4-03-12 at 1410 hours, staff A1 confirmed that the policy/procedure failed to indicate an ongoing relationship with an area hospital in the event of a community disaster, failed to indicate the center responses for specific emergencies, and failed to ensure that disaster drills will be conducted in addition to quarterly fire drills at the center.</p>						

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S1222	<p>410 IAC 15-2.5-8 RADIOLOGY SERVICES 410 IAC 15-2.5-8(e)</p> <p>(e) Safeguards for patients, personnel, and public must be specified, including, but not limited to, the following:</p> <p>(1) Proper safety precautions must be maintained against radiation hazards in accordance with the center's radiation and safety program(s).</p> <p>(2) Hazards and faulty equipment identified must be promptly corrected in accordance with current standards of practice and applicable federal and state rules, including, but not limited to, collimation and filtration and evaluations of equipment performance.</p> <p>Based on document review, the center failed to ensure that proper radiation safety precautions were maintained and that services were provided in a safe and effective manner and reported through the safety program.</p> <p>Findings:</p> <p>1. The policy/procedures Radiologic Services (approved 3-12) failed to establish a radiation safety program including the following:</p> <p>A. the location where staff shall wear a radiation exposure monitor badge</p> <p>B. the location for proper storage of</p>		S1222	<p>OR Charge nurse updated radiology policy and procedure to include deficiency issues. OR Charge Nurse is responsible for compliance.</p>		04/23/2012	

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	<p>monitoring badges when not in use</p> <p>C. screening for any potentially pregnant female patient to determine fetal risk</p> <p>D. periodic testing of protective lead shielding</p> <p>E. specific information/training for operating room personnel regarding hazards of radiation exposure and techniques to minimize exposure.</p> <p>2. On 4-04-12 at 1100 hours, staff A3 confirmed that the policy/procedure lacked the indicated provisions and failed to establish a radiation safety program.</p>						